K091670
1 of 2

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SPECIAL PREMARKET NOTIFICATION
[510(K)] Summary- *(Bundled Submission)*

Submitter:	Becton Dickinson Infusion Therapy Systems, Inc.
Address:	9450 South State Street Sandy, UT 84070
Contact Person:	Justice Alder Specialist, Regulatory Affairs
Telephone Number: **Fax Number:**	801-565-2662 801-565-2749
Date Summary Prepared:	June 2, 2009
Trade Names:	BD L-Cath™ Single Lumen BD L-Cath™ Dual Lumen BD L-Cath™ Midline
Common Name:	Peripherally Inserted Central Catheter (PICC); Intravascular Catheter (IV Catheter)
Classification Name:	Catheter, Intravascular, Therapeutic, Long- Term Greater Than 30 Days (LJS/FOZ)
Unmodified/Predicate Device:	(K925979) Dual lumen L-Cath® Catheter System (K920755) L-Cath Peel Away Systems Catheter

Description of the device:

Becton Dickinson obtained the L-Cath™ catheter product lines through the purchase of Luther Medical Inc, a California based company, in January 1999. Luther Medical obtained market clearance from the US Food and Drug Administration (FDA) during 1993 for the L-Cath™ peripherally inserted central catheters through the premarket notification [510(k)] process. Becton Dickinson currently markets the L-Cath single lumen, dual lumen, and midline catheters. These catheters have a plastic bushing material that is used for the purpose of catheter assembly and/or extension tubing with a female luer lock adapter.

The primary modification addressed in this 510(k) submission relates to a material modification in the bushing component. The modifications to the devices pertain to a

modified bushing material that is known as PC Makrolon RX2530-1118, which has been tested by Becton Dickinson's supplier and meets FDA & ISO standards. The bushing material is used in all three types of catheters to join the tubing to the female luer lock adapter. The material modification affects only the bushing that is seated within the luer adapters of the BD L-Cath™ PICC and BD L-Cath™ Midline products. The formulation modification is a linear polycarbonate with the same end groups, formulation, additives, and colorants. The only difference being a higher molecular weight for the modified material.

Intended Use of the L-Cath™ single lumen, and BD L-Cath™ dual lumen catheter devices: [21 CFR Part 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES; General Hospital and Personal Use Therapeutic Devices Sec. 880.5970]

The BD L-Cath™ single and dual lumen peripherally inserted central catheters intended use shall be for the administration of fluids, medications, and nutrients; the sampling of blood; and monitoring blood pressure and temperature intravenously.

Intended Use of the BD L-Cath™ Midline catheter devices:

The BD L-Cath™ Midline™ Catheter intended use shall be for the administration of fluids, medications, and nutrients; the sampling of blood; and monitoring blood pressure and temperature intravenously.

Technological Characteristics Comparison:
The L-Cath products have the same technological characteristics with no changes in part geometry or performance, and have the same formulation, additives, and colorants as the current device material. The only difference being a higher molecular weight in the formulation change which is not evident to the end user.

Nonclinical Tests Support Substantial Equivalence:
The following qualities of the three devices are the same and support substantial equivalence: Indications for use, fundamental scientific technology, gauge sizes of the devices, visualization of blood return and potential for blood exposure during use.

Conclusions from Nonclinical Tests:
The intended use and technological characteristics of the BD L-Cath™ products described in this submission have not been altered and therefore have remained the same since receiving their original 510(k) approval from the FDA.

The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence found in the Federal Food, Drug, and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without premarket approval or reclassification. A determination of

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 1 2009

Becton Dickinson and Company
C/O Ms. Justice Alder
Regulatory Affairs Specialist
Becton Dickinson Infusion Therapy Systems, Incorporated
9450 South State Street
Sandy, Utah 84070

Re: K091670
Trade/Device Name: BD L-Cath™ Midline™ Catheter
BD L-Cath™ Single Lumen
BD L-Cath™ Dual Lumen
Peripherally Inserted Central Catheters (PICC)
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS, FOZ
Dated: June 2, 2009
Received: June 9, 2009

Dear Ms. Alder:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony D. Watson for

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K091670
1 of 1

Indications for Use

510(k) Number (if known): K091670

Device name: BD L-Cath™ Midline™ Catheter

Indications for Use: The intended use shall be for the administration of fluids, medications, and nutrients; the sampling of blood; and monitoring blood pressure and temperature intravenously.

Prescription Use____X_____ AND/OR Over-the-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IS NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K091670

K091670
1 of 1

Indications for Use

510(k) Number (if known): K091670
K091670

Device name: BD L-Cath™ Single Lumen/
BD L-Cath™ Dual Lumen
Peripherally Inserted Central Catheters (PICC)

Indications for Use: The intended use shall be for the administration of fluids, medications, and nutrients; the sampling of blood; and monitoring blood pressure and temperature intravenously.

Prescription Use____X_____ AND/OR Over-the-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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Infection Control, Dental Devices

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